EXHIBIT 412

RITE AID
DISTRIBUTION CENTER

DEA REGULATORY GUIDELINES

DISTRIBUTION / CUSTOMER SUPPORT CENTER
PRESCRIPTION DRUG SOPS

REGULATORY GUIDELINES

POLICY

RITE AID is committed to meeting the legal and regulatory requirements of those locations where the company conducts operations. In the case of drug substances and products regulated as Controlled Substances and chemicals regulated as Listed chemicals by the U.S. Drug Enforcement Administration (DEA), it is the policy of RITE AID to apply these requirements to all operations where such drug substances, drug products and Listed chemicals are manufactured, packaged, and/or distributed.

Therefore, the following DEA REGULATORY GUIDELINES were prepared in response to a need for a single source of current information for RITE AID regarding Drug Enforcement Administration (DEA) policies and the requirements of the Comprehensive Drug Abuse Prevention Act (Public Law 91-5132), otherwise known as the Controlled Substances Act of 1970 (CSA) and the implementing regulations.

The CSA and its' regulations affect every aspect of a DEA registrant's ordering, receiving, storage, returns to the supplier, and disposal of products that contain Controlled Substances or List I chemicals. Because the vast majority of all legitimate medical use of Controlled Substances at some point passes through a distributor, this represents a major focus of DEA enforcement attention and investigative activity.

If violations are discovered by the DEA, administrative, registration, civil, or criminal actions are considered and may be applied. The CSA and the implementing regulations and the DEA's enforcement of them are so strict that there can be DEA actions even for recordkeeping violations in the absence of any evidence of diversion.

RITE AID is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility for compliance cannot be abdicated or transferred to anyone else. The legislative and social intent of regulating Controlled Substances and products that contain List I chemicals is consistent with the mission of RITE AID in serving the public good. To achieve these important goals, RITE AID supports the proper and appropriate use of Controlled Substances and products that contain List I chemicals for legitimate use and seeks to eliminate any and all diversion of Controlled Substances and products that contain List I chemicals.

In order for RITE AID facilities to ensure that they are in full compliance with DEA requirements, RITE AID facilities will undertake selected internal reviews to assure regulatory compliance and compliance with DEA requirements. The more frequently all aspects of DEA compliance are reviewed, the better the chances that RITE AID will be in compliance and not experience problems when DEA or others review our operation.

Site Administration

Each RITE AID registrant handling Controlled Substances will designate a DEA Coordinator or DEA Point Person. The DEA Coordinator/Point Person will implement the required systems and procedures and ensure that RITE AID site operations are consistent with the DEA REGULATORY GUIDELINES.

TABLE OF CONTENTS

Section

I. GLOSSARY OF TERMS

II. DEA REGISTRATION APPLICATIONS

III. POWER OF ATTORNEY FOR REGISTRATION APPLICATIONS

IV. ORDERING AND DOCUMENTING RECEIPT OF CONTROLLED SUBSTANCES

V. RECEIVING CONTROLLED SUBSTANCES

- RECORDS
- RECEIVING

VI. SUSPCIOUS ORDER MONITORING

VII. REGISTRATION VERIFICATION

VIII. DELIVERING OF CONTROLLED SUBSTANCES AND SELECTION OF COMMON OR CONTRACT CARRIERS

IX. DISTRIBUTION FOR CONTROLLED SUBSTANCES

- RECORDS
- PICKING
- PACKING

X. HANDLING AND RECORDS FOR UNSOLICITED RETURNS

XI. DISPOSITION OF CONTROLLED SUBSTANCES

XII. EMPLOYEE BACKGROUND CHECKS

XIII. REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES

XIV. MAINTAINING A PERPETUAL INVENTORY FOR SCHEDULE III, IV AND V CONTROLLED SUBSTANCES

XV. CONDUCTING DEA INVENTORIES

- BIENNIAL INVENTORY
- ADJUSTMENTS

XVI. MAINTAINING ACCURATE RECORDS - FILING AND MAINTENANCE

Section

XVII. CENTRAL RECORDS

XVIII. SECURITY FOR CONTROLLED SUBSTANCES

- PHYSICAL
- ALARMS
- ACCESS
- CCTV CAMERAS & MONITORS

XIX. INTERNAL AUDITS FOR SCHEDULE III, IV AND V CONTROLLED SUBSTANCES

XX. POLICY REVIEW AND REVISION AND ADMINISTRATIVE ACTIONS

XXI. HOW TO HANDLE A DEA INSPECTION

XXII. COORDINATION WITH REGULATORY AND ENFORCEMENT AGENCIES

XXIII. STAFF TRAINING

XXIV. LIST I CHEMICALS

- RECORDS
- REGISTRATION
- REPORTS

XXV. VISITOR CONTROLS

XXVI. ARCOS

XXVII. FREIGHT FORWARDING

DEA REGULATORY GUIDELINE

I. GLOSSARY

A. CONTROLLED SUBSTANCES

Definitions Relating To Controlled Substances (Reference is made to Sec. 1300.01 Code of Federal Regulations, Food and Drugs 21 Part 1300 to End, Revised as of April 1, 2000) and the Controlled Substances Act (CSA). Please refer to the CSA and the implementing regulations for additional information.

1. Act means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951). This is the authority that the DEA operates under.

2. Administration means the Drug Enforcement Administration (DEA). The DEA is an administration within the Department of Justice.

3. Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

4. Agent means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser (DEA registrants).

5. Anabolic Steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins and corticosteroids) that promotes muscle growth.

6. ARCOS - Automation of Reports and Consolidated Order Systems. ARCOS reporting is required for U.S. manufacturers, repackers/relabelers of bulk or finished dosage forms for all Schedule I or II compounds, narcotic Schedule III and psychotropic Schedule III and IV compounds and for distributors of Schedule I and II and narcotic Schedule III compounds.

7. Basic Class is a term that refers to Controlled Substances listed in Schedules I and II.

8. Commercial container means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a

commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of Controlled Substances.

9. Controlled Substance has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).

10. Customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.

11. DEA Regional Administrator - "Special Agent in Charge"

    a. DPM - Diversion Program manager, located at the DEA divisional office.

    b. DGS - Diversion Group Supervisor, located at various DEA officers.

12. Dispense means to deliver a Controlled Substance to an ultimate user or research subject by the lawful order of a practitioner.

13. Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a Controlled Substance.

14. Distributions - means by which perpetual inventory is change by any of the following means: Invoice, 106, 41, Return to Vendor or sent to Reverse Distributor.

15. Distributor means a person who forwards a controlled substance, List I Chemical and/or a product that contains a List I chemical through authorized/legitimate channels. A distributor may not relabel or repackage the products from the original labeled commercial container that holds the product received from their vendor, prior to distribution. A distributor may only ship the drugs for distribution, in its' original labeled commercial container by securing into a shipping container, FedEx box, UPS package, etc.

16. Diversion means the unauthorized removal of Controlled Substances or List I chemicals from the approved distributed chain.

17. Export means with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

18. Exporter includes every person who exports, or who acts as an export broker for exportation of, Controlled Substances listed in any schedule.

19. Freight forwarding (as used in DEA's regulatory meaning does not have the same meaning that it carries in the transportation/distribution industry). Means a separate facility operated by a distributing registrant through which sealed, packaged Controlled Substances and listed chemicals in unmarked shipping containers (i.e., the containers do not indicate that the contents include Controlled Substances) are, in the course of delivery to or return from customers, transferred in less than 24 hours. A distributing registrant who operates a
freight forwarding facility may use the facility to transfer Controlled Substances from any location the distributing registrant operates that is registered with the DEA to manufacture, distribute, or import Controlled Substances, or, with respect to returns, registered to dispense Controlled Substances, provided that the notice required by Section 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved.

For purposes of this definition, a distributing registrant is a person who is registered with the DEA as a manufacturer, distributor, and/or importer.

20. Immediate Precursor means a substance which the Attorney General has by regulation designated as being the principal compound used or produced primarily for use in the manufacture of a Controlled Substance; is an immediate chemical intermediary used or likely to be used in the manufacture of such Controlled Substances; and the control of which is necessary to prevent, curtail or limit the manufacturer of such Controlled Substance.

21. Import means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

22. Importer includes every person who imports, or who acts as an import broker for importation of, Controlled Substances listed in any schedule.

23. Individual Practitioner means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted by the U.S., or the jurisdiction in which he/she practices; to dispense a Controlled Substance (does not include a pharmacist, pharmacy or an institutional practitioner).

24. Initial Inventory Date means the date activities with Controlled Substances begin (not the date of registration or

date of application for registration).

25. Institutional Practitioner means a hospital or other person licensed, registered or otherwise permitted, by the U.S. or jurisdiction in which it practices, to dispense a Controlled Substance.

26. Inventory means all factory and branch stocks in finished form of a basic class of Controlled Substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter or distributor).

    (a) Biennial Inventory means a physical inventory conducted on the initial inventory date and another within two years.

    (b) Daily Use Inventories mean a physical inventory maintained for each controlled that list receipts, deductions and physical inventory on a daily basis.

    (c) ARCOS Year Ending Inventory means that Manufacturers and distributors are required to report their annual inventories of specific controlled substances. The CFR requires that an ***annual*** inventory of each reportable controlled substance be taken on December 31st of each year and filed with DEA (ARCOS) ***no later than January 15th*** of the following year.

27. Isomer means the optical isomer, except as used in Sec. 1308.11(d) and Sec. 1308.12(b)(4) of the regulations. As used in Sec. 1308.11(d) of the regulations, the term isomer means the optical, positional, or geometric isomer. As used in Sec. 1308.12(b)(4) of the regulations, the term isomer means the optical or geometric isomer.

28. Jurisdiction means of the United States means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

29. Label means any display of written, printed, or graphic matter placed upon the commercial container of any Controlled Substance by any manufacturer of such substance.

30. Labeling means all labels and other written, printed, or graphic matter:

    (a) Upon any Controlled Substance or any of its commercial containers or wrappers, or

(b) Accompanying such Controlled Substance.

31. Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. The term manufacturer means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

32. Methamphetamine Control Act (MCA) means the act establishing ephedrine, pseudoephedrine, phenylpropanolamine and combination ephedrine products as regulated List 1 chemicals, and requires that reports of certain distributions to non-regulated persons be reported each month.

33. Narcotic drug means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(a) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(b) Poppy straw and concentrate of poppy straw.

(c) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(d) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(e) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(f) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b)(31)(i) through (v) of the regulations.

34. Net disposal means, for a stated period, the quantity of a basic class of Controlled Substance distributed by the

registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of Controlled Substance or a non-Controlled Substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of Controlled Substance or a non-Controlled Substance or in the manufacture of dosage forms of that basic class.

35. Opiate means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

36. Opium Poppy means the plant of the species Pavaver somniferm L., except the seed thereof

37. Pharmacist means any pharmacist licensed by the State to dispense Controlled Substances, including any person authorized by a State to dispense Controlled Substances under the supervision of the licensed pharmacist.

38. Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

39. Primary Record - a document designated for receiving or distribution that contains all information as required by the regulations.

40. Prescription means an order for medication dispensed to or for the ultimate user.

41. Poppy Straw means all parts, except the seeds, of the opium poppy, after mowing.

42. Production means the manufacture, planting, cultivation, growing, or harvesting of a Controlled Substance.

43. Purchaser means any registered person entitled to obtain and execute order forms pursuant to Section 1305.04 and Section 1305.06.

44. Quota means a quantitative expression of the amount of each Controlled Substance that may be produced during the calendar year. There are three types of quotas as follows:

    (a) The aggregate production quota is a quantitative expression of the amount of each Controlled Substance

that may be produced during the calendar year to provide for: the estimated medical, scientific, research, and the industrial needs for the U.S.; the lawful export requirements; and the establishment and maintenance of reserve stocks.

(b) The manufacturing quota is the quantity of Controlled Substances which an individual manufacturer may produce during the calendar year. Manufacturing quotas are determined on the basis of the manufacturer's estimated disposal inventory and other special requirements. Additional factors considered are the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the production cycle, the inventory position as well as economic availability of raw materials, along with yield and stability problems. Emergencies also have an effect in the determination of the manufacturing quota.

(c) Procurement quotas are issued annually by the "share-of-the-market theory" to the various procurement quota applicants. Share-of-the market is determined by calculating the percentage of business a firm did in a particular basic class the previous year as compared to the total disposal of all the firms utilizing that same basic class.

45. Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

46. Register and registration refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

47. Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

48. Schedule I Controlled Substances means a drug or substance that has a high potential for abuse, has no currently accepted medical use in treatment in the U.S., and lacks accepted safety under medical supervision. Listed in 21 CFR, Part 1308.11.

49. Schedule II Controlled Substances means a drug or substance that has a high potential for abuse, has a currently accepted medical use for treatment in the U.S., and abuse of the drug may lead to severe psychological or physical dependence. Listed in 21 CFR Part 1308.12.

50. Schedule III Controlled Substances means a drug or substance that has a potential for abuse less than the drugs listed in schedule I and II, has a currently accepted medical use in the U.S., and abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. Listed in 21 CFR Part 1208.13.

51. Schedule IV Controlled Substances means a drug or substance with a low potential for abuse relative to the drugs in Schedule III, has a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to limited physical or psychological dependence relative to the drugs in Schedule III. Listed in 21 CFR Part 1208.14.

52. Schedule V Controlled Substance means a drug or substance with low potential for abuse relative to the drugs in Schedule IV, has a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to limited physical or psychological dependence relative to drugs in Schedule IV. Listed in 21 CFR Part 1308.15.

53. Supplier means any registered person entitled to fill order forms pursuant to Sec. 1305.08 of the regulations.

54. Ultimate User means a person who has lawfully obtained, and who possesses, a Controlled Substance for his own use or for the use of a member of his household or for an animal owned by him or member of his household.

B. LIST I CHEMICALS

Definitions Relating To List I Chemicals (Reference is made to Sec. 1300.01 Code of Federal Regulations, Food and Drugs 21 Part 1300 to End, Revised as of April 1, 2000) and the Controlled Substances Act.

1. Act means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951) as amended.

2. Administration means the Drug Enforcement Administration.

3. Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

4. Broker and trader mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by

(a) Negotiating contracts;
(b) Serving as an agent or intermediary; or
(c) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

5. Chemical export means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

6. Chemical exporter is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

7. Chemical import means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

8. Chemical importer is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

9. Chemical mixture means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

10. Customs territory of the United States means the several States, the District of Columbia, Puerto Rico.

11. Encapsulating machine means any manual, semiautomatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

12. Established business relationship with a foreign customer means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or

business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of 15-day advance notice requirements of Sec. 1313.24 of the regulations:

(a) The name and street address of the chemical exporter and of each regular customer;

(b) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(c) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(d) The duration of the business relationship;

(e) The frequency and number of transactions occurring during the preceding 12-month period;

(f) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;

(g) The method of delivery (direct shipment or through a broker or forwarding agent); and

(h) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

13. Established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of Sec. 1313.15 of the regulations:

(a) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) The frequency and number of transactions occurring during the preceding 12 month period.

14. Hearing means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to

sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

15. International transaction means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

16. Jurisdiction of the United States means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

17. Listed chemical means any List I chemical or List II chemical.

18. List I chemical means a chemical specifically designated by the Administrator in Sec. 1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the Act and is important to the manufacture of a Controlled Substance.

19. List II chemical means a chemical, other than a List I chemical, specifically designated by the Administrator in Sec. 1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the Act.

20. Name means the official name, common or usual name, chemical name, or brand name of a substance.

21. Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

22. Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

23. Register and registration refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

24. Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

25. Regular customer means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported

to the Administration subject to the criteria established in Sec. 1300.02(b)(12).

26. Regular importer means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

27. Regulated person means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

28. Regulated transaction means:

(a) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or

(b) if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, and 1313 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of

the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless

- The drug contains ephedrine or its salts, optical isomers, or

- The Administrator has determined pursuant to the criteria in 1310.10 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a Controlled Substance; and

- The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical.

(v) Any transaction in a chemical mixture listed in Sec. 1310.13 of this chapter.

(vi) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

29. Retail distributor means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine, or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. For the purposes of this paragraph, sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through 5399 and 5499, and a drug store is an entity within SIC code 5912.

30. Tableting machine means any manual, semi-automatic, or fully

automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

DEA REGULATORY GUIDELINE

II. DEA REGISTRATION APPLICATIONS

PURPOSE: To ensure that the correct procedure for obtaining a Drug Enforcement Administration distributor registration is implemented and that an authorized person signs the application for registration.

PROCEDURE: NEW LICENSES

1. Prior to distributing Controlled Substances, RITE AID corporate office must apply on DEA Form 225 (registration application) and obtain a DEA registration for any new facility.

2. Registration applications (DEA form 225) are obtained by RITE AID corporate office through a local DEA office, or by writing to the Registration Unit, Drug Enforcement Administration, Attn: Registration Section/ODR, Post Office Box 2639, Springfield, Virginia, 22152-2639.

3. Each DEA application for registration, attachment, or other document filed as part of the application, must be signed by the applicant; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity.

4. Please verify with Rite Aid's Government Affairs department to ensure that the individual signing the registration application is an officer of the corporation.

5. Modification and Transfer of Registration

   Modifications and transfer of a DEA registration or state license may only be accomplished by Rite Aid's corporate licensing department.

PROCEDURE: RENEWALS

6. Upon renewal, DEA Form 225a will be mailed, as applicable, to each RITE AID registered distributor location approximately 60 days before the expiration date of their registration. If any registrant does not receive the renewal form within 45 days before the expiration date of their registration, the registrant must promptly give notice to the RITE AID corporate office. A Form 225a will then be requested, by RITE AID, in writing from the Registration Unit of the DEA.

7. Each RITE AID facility must review and forward the registration or re-registration application to the corporate licensing department. The RITE AID licensing department will

ensure the application includes all information called for in the form, unless the item is not applicable, in which case this fact must be indicated.

a. Modification in Registration

RITE AID corporate licensing department may apply to modify a registration to change a name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Attn: Registration Section/ODR, Post Office Box 2639, Springfield, Virginia, 22152-2639.

The letter must contain the registrant's name, address, and registration number as printed on the certificate of registration, and the new name or address, and must be signed by a corporate officer. No fee is required to be paid for the modification. The request for modification is handled by the DEA in the same manner as an application for registration. If the modification in registration is approved, the DEA will issue a new certificate of registration (DEA Form 223) to the registrant. The new registration must be maintained with the old certificate of registration until expiration.

b. Transfer of Registration

a) Transfer and/or termination of a DEA registration must be immediately communicated to Rite Aid's Government Affairs Department.

b) A Rite Aid DEA registration terminates if and when a Rite Aid DEA registrant ceases legal existence, or discontinues business, except upon conditions that the DEA may specifically designate and then only pursuant to written consent. No registration or any authority conferred may be assigned or otherwise transferred except upon such conditions as the DEA may specifically designate and then only pursuant to the DEA's written consent. The Rite Aid registrant that ceases legal existence or discontinues business or professional practice must notify Rite Aid's Government Affairs Department and the corporate licensing department as well, prior to one of the above activities taking place.

XVII. After coordination with Rite Aid's departments of Licensing and Government Affairs, the corporate office will handle the required communication with the DEA.

DEA REGULATORY GUIDELINE

III. POWER OF ATTORNEY FOR EXECUTING A DEA APPLICATION

PURPOSE: To insure that the correct procedure for executing DEA applications for registration is implemented by the corporate office.

PROCEDURE:

1. RITE AID may authorize one or more individuals (the utilization of a non-corporate officer is the exception), who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the DEA a Power of Attorney (POA) for the individual being authorized by the applicant to sign the application for registration.

2. The Power of Attorney must be issued and signed by the corporate officer who is authorized to sign the DEA application for registration (See DRG DEA Registration Applications) and must contain the signature of the individual being authorized to sign the application. The Power of Attorney is valid until revoked by the applicant.

3. **An original copy Power of Attorney must accompany the DEA application for registration to the DEA.**

4. Maintain an original copy of the Power of Attorney at the registered location with a copy of the DEA application for registration or re-registration.

NOTE: The Power of Attorney described in this operating procedure is different than the Power of Attorney required for executing the DEA Form 222.

DEA REGULATORY GUIDELINE

IV. RECEIVING AND DOCUMENTING RECEIPT OF CONTROLLED SUBSTANCE MEDICATIONS

PURPOSE: To enable RITE AID facilities to receive and document the receipt of Schedule III, IV and V Controlled Substances in a manner that meets the regulatory compliance.

PROCEDURE:

Schedule III, IV and V Medications

1. RITE AID corporate pharmacy replenishment department reviews the Schedule III, IV and V Controlled Substance inventory levels.

2. Based upon current inventory levels and usage and other relevant factors, corporate replenishment develops an order for the Schedule III, IV and V Controlled Substances. The order is then forwarded to the appropriate vendor/supplier.

   When Schedule III, IV and V orders are received at the facility, a receiving (Exemptee in CA) employee verifies and signs for the delivery. The delivery is then forwarded to the appropriate processing area. Designated receivers will process and verify all Controlled Drug deliveries following site specific procedures.

   If the entire order is correct, the designated employee signs and dates (reflecting the actual date on which the Controlled Substances are received at the facility) the packing list/invoice/purchase order. The original packing list/invoice/purchase order is maintained separately in a secure storage location. (**See DRG XVI. MAINTAINING ACCURATE RECORDS**).

   If there are any discrepancies between the packing list/invoice/purchase order and the items received, the designated individual notes the discrepancies on the vendor packing list and contacts their designated DEA point person(s). The Designated DEA person(s) contact corporate pharmacy replenishment immediately. (**See DRG XIII. REPORTING LOSSES AND THEFTS OF CONTROLLED SUBSTANCES**).

3. Primary receiving records, in addition to designating the controlled drugs received (name, quantity, dosage form, strength, size and number of commercial containers), must list the name, address, DEA registration number of the vendor/supplier and the actual date of receipt.

3. The original Schedule III, IV and V receiving records will be maintained at the registered location.

DEA REGULATORY GUIDELINE

V. RECEIVING OF CONTROLLED SUBSTANCES

PURPOSE: To establish receiving procedures for Controlled Substances to assure compliance with all DEA requirements.

PROCEDURE:

1. The receiving documentation for all Controlled Substances received in the warehouse must include the name, address and DEA number of the vendor from which the product is received.

2. Only receiving (Exemptee in CA) designated personnel may sign for controlled receipts.

3. The actual date received must be recorded on the receiving documentation. If the product is detailed the day after receipt, under no circumstance is that date to be recorded as the receipt date. This should be recorded as the processed date.

4. Controlled Substances will be immediately unloaded and taken to the approved drug area. Authorized personnel within the drug area then take possession of the Controlled Substances for further processing.

5. No Controlled Substances are to be left unattended and/or stored on the dock. The product is to be under observation until it is delivered and secured in the approved Controlled Substances cage.

6. Warehouse management or the designee must validate the receipt verifying the shipper's DEA number, name and address in a noted line on the receiving document.

DEA REGULATORY GUIDELINE

VI. SUSPICIOUS ORDER MONITORING

PURPOSE: To provide for monitoring of all Controlled Substances orders so as to detect suspicious orders.

PROCEDURE:

1. All orders containing Controlled Substances are reviewed and verified for order quantity and size to not exceed the determined order history threshold. Any order exceeding the threshold is immediately forwarded to the department manager for further investigation.

2. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

3. A review is performed to determine the legitimacy of the order. Appropriate documentation of the review is maintained on file.

4. Any order which is determined to be suspicious will be immediately reported to the corporate office, who will notify the local DEA Field Division Office of the Administration.

5. If a suspicious order is reported to Corporate, the Corporate Government Affairs will determine whether to "ship" or "do not ship".

6. All discussions, investigations and reports will be maintained in the file designated "Suspicious Orders".

DEA REGULATORY GUIDELINES

VII. REGISTRATION VERIFICATION

PURPOSE: To establish a system for verifying a pharmacy location's DEA registration.

PROCEDURE:

1. A valid DEA registration in the schedule of the products ordered is required for all pharmacy locations ordering Controlled Substance products. A current copy of the DEA license for each pharmacy location must be maintained on file by the corporate licensing department.

2. The pharmacy's shipping information must correspond with the information as it appears on their DEA registration.

3. Controls must be utilized to prevent controlled product from being shipped to a pharmacy whose DEA registration has expired.

4. Orders may not be processed and shipped unless the pharmacy's DEA registration is current and will not be expired upon receipt of the Controlled Substances.

DEA REGULATORY GUIDELINE

VIII. DELIVERY OF CONTROLLED SUBSTANCES AND SELECTION OF COMMON OR CONTRACT CARRIERS

PURPOSE: To ensure secure delivery of Controlled Substances while maintaining reliable documentation of the transaction.

PROCEDURE:

1. Common or contract carriers must be selected which provide adequate security to guard against in-transit losses.

2. All contracts for delivery services must include language pertaining to the adherence of Rite Aid delivery policies and procedures.

3. When shipping Controlled Substances, the shipping container labeling will not disclose the contents as being a Controlled Substance.

4. Each tote, box, other container, etc., will be prepared for delivery with a tamper-proof seal, tape, etc., and shall be accompanied by a "Job/Delivery Manifest" indicating the information necessary for the customer to confirm the contents of the delivery. All delivery tickets will be prepared in triplicate.

5. The delivery totes containing Controlled Substances will be sealed under continual direct supervision within the Controlled Substance storage enclosures.

6. To confirm chain of custody throughout the delivery process, the delivery manifest will be signed by each party that takes possession of the delivery. At time of pickup, the driver acknowledges receipt of the package. This copy of the job ticket is maintained at Rite Aid. The two remaining copies are retained by the facility.

7. Upon delivering the package to the pharmacy, the driver obtains a signature from a pharmacy representative, leaves one copy with the customer and returns the signed copy to Rite Aid. The transportation supervisor, or an employee designated in writing, compares the copies to determine proof of delivery. Paired and stapled copies are filed and maintained in a readily retrievable manner.

8. Delivery tickets will be retained for a minimum of two years.

9. In the event that the delivery manifest copy is not returned, the transportation supervisor or their designee contacts the

responsible driver to determine the reason. This discussion will be documented and reviewed by the General Manager or their designee.

10. All contracts for delivery services should include language pertaining to the adherence of Rite Aid delivery policies and procedures. Also, all delivery service personnel should have received, at the services' expense, the proper background checks as found in **DRG XII. Employee Background Checks.**

11. It is imperative that all procedures listed above are followed. Contract drivers should be given these procedures and acknowledge their acceptance and adherence to their content. Frequent policy violations occurring in the delivery of Controlled Substances, non-controlled prescription drugs and other merchandise will be considered grounds for immediate termination of the contract.

12. Thefts or significant losses are to be reported immediately. (**See DRG XIII. REPORTING LOSS OR THEFT OF CONTROLLED SUBSTANCES**)

DEA REGULATORY GUIDELINE

IX. DISTRIBUTION OF CONTROLLED SUBSTANCES

PURPOSE: To allow for the distribution or transfer of Controlled Substances in accordance with applicable regulations between DEA registrants.

PROCEDURE:

Schedule III, IV and V Controlled Substances

1. The distribution center must maintain complete records for the distribution or return of Schedule III, IV and V Controlled Substances to another DEA registrant.

2. The distribution record must list:

   a. The name, address and DEA registration number of the customer or vendor/supplier;

   b. The actual date of distribution; and

      1) The date the Controlled Substances actually depart the distribution center.

      2) The actual date of the distribution must be recorded on the distribution documentation. If the shipment is processed the day prior to distribution, documentation should be recorded in the appropriate manner but under no circumstance is that date to be recorded as the distribution date.

   c. The name, dosage form, strength, quantity and number commercial containers.

3. The Controlled Substances will be picked and packaged in the Controlled Substances cage.

4. Prior to packing and sealing the tote, the Controlled Substances will be checked against the pick ticket to confirm the order is correct.

5. The tote will be sealed by such means (banding or seals) that evidence of tampering will be visible.

6. The sealed totes will be transported to the dock for placement in the delivery trucks per site guidelines.

7. If this process is applicable in a building, the movement will be by employees specifically designated in writing by name and/or job title.

8. Only warehouse personnel designated in writing by name and or job title assigned to the distribution area may monitor Controlled Substance out-bound packages.

9. No Controlled Substance distributions are to be left unattended on the dock. The product is to be under observation of an employee specifically designated in writing by name and/or job title until it is placed on the delivery trucks, the trucks are secured and sealed and the trucks depart.

10. Any outbound Controlled Substance packages that are not distributed must be returned to the approved storage enclosures.

DEA REGULATORY GUIDELINES

X. HANDLING AND RECORDS FOR UNSOLICITED RETURNS

PURPOSE: To establish a procedure for the proper handling and documentation for unsolicited returns.

PROCEDURE:

1. It is the Distribution Center's policy not to accept controlled drug returns, unless an exception has been made by Corporate. However, there are instances in which the Distribution Center's receive unsolicited returns.

2. Upon receipt, document the findings and report to Corporate. Return product to Store if it can be identified. If the Store cannot be identified, ship to reverse distributor for processing.

3. If a return is visibly damaged, a hazardous waste assessment must be done.

4. Returned product will be immediately marked for destruction if any of the following conditions exist:

    a. It is indicated the product has been held, stored or shipped under questionable conditions.

    b. Based on visual inspection, the product's container, carton, tamper-evident seals, or labeling indicates possible product contamination.

    c. The product is short-dated or expired.

    d. A signed statement is not provided by the customer that states that the product was maintained at the storage conditions as required by the label.

5. Controlled Substances are immediately identified and separated from other product. An exact count is performed of the contents and recorded.

6. Controlled Substances are immediately moved to the cage and placed in **a** well-defined quarantine location to await disposition.

7. Controlled Substances must be disposed of by a method approved by the DEA or the appropriate state agency or transferred to a DEA registered reverse distributor **(See DRG XI. Disposal of Controlled Substances).**

DEA REGULATORY GUIDELINE

XI. DISPOSAL OF CONTROLLED SUBSTANCES

PURPOSE: To provide a system for the destruction and disposal of rejected, damaged, or expired Controlled Substances according to DEA regulation.

PROCEDURE:

1. All rejected, damaged, or expired Controlled Substances will be quarantined and held for destruction or returned to the vendor or forwarded to a DEA registered reverse distributor.

2. Controlled Substance may be destroyed by private firms that are registered with the DEA as "reverse distributors". The reverse distributors will handle the disposal in accordance with DEA and EPA requirements and standards. The transfers of Controlled Substances are considered a disposition from the distributor's DEA registration to the reverse distributors DEA registration, utilizing the required distribution records.

3. Assure that an environmentally approved disposal method is utilized. Conduct a compliance review of the reverse distributor prior to selection.

4. Controlled Substances are <u>not</u> to be placed and/or thrown into the garbage, flushed and/or given to a non-DEA registered disposal company.

5. The registrant desiring to dispose of controlled drugs through a reverse distributor must list the controlled drugs on a triplicate form that contains both registrants DEA numbers, as well as all pertinent product information.

   <u>Schedule III, IV and V</u> - A distribution record that lists the name, address and DEA registration number of the registrant receiving the Controlled Substances, the actual date of distribution, name of the drug, dosage form, strength, quantity and number of commercial containers.

6. Properly label and seal the containers/boxes holding Controlled Substances. The Controlled Substances must be stored in a substantially constructed, controlled and limited access DEA approved storage enclosure. Maintain a complete inventory of the Controlled Substances.

7. Maintain a log recording the disposition of the Controlled Substances.

8. Check with the appropriate state authority to determine if there are any state restrictions or controls on disposition.

DEA REGULATORY GUIDELINE

XII. EMPLOYEE BACKGROUND CHECKS

PURPOSE: To obtain the information necessary to prohibit the employment of an individual who does not meet the regulatory requirements mandated by the Controlled Substances Act and the implementing regulations.

PROCEDURE:

1. It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall Controlled Substances security. In this regard, it is believed that conviction of crimes and unauthorized use of Controlled Substances are activities that are proper subject for inquiry. It is, therefore, assumed that the following questions will become part of Rite Aid comprehensive employee screening program:

   Question: Are you now or have you ever been excluded from participating in Medicare, Medicaid or any Federal Health Care program? If so, provide a detailed explanation on the back of this screening form.

   Question: Is there currently a proceeding pending against you by the Drug Enforcement Agency, Health Care Finance Administration, State Board of Pharmacy or any other Federal or State government Agency? If so, provide a detailed explanation on the back of this screening form

   Question: Are you now, or have you ever been, precluded by the Drug Enforcement Administration from dispensing controlled substances because of a felony conviction related to the handling of these drug products? If so, provide a detailed explanation on the back of this screening form.

   Question: Have you ever entered into a consent decree or been found guilty by a State Board of Pharmacy for offenses to the practice of pharmacy? If so, provide a detailed explanation on the back of this screening form.

Question: Have you ever been the subject of discipline with respect to your pharmacy credential? If so, provide a detailed explanation on the back of this screening form.

Question: Have you ever been the subject of/involved in an inquiry or investigation? If so, provide a detailed explanation on the back of this screening form.

Question: Are there any limits or restrictions on your ability to engage in any work as it relates to your pharmacy credential? If so, provide a detailed explanation on the back of this screening form.

2. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to Controlled Substances exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment.

3. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualification.

4. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

5. Employees will be advised that if they have knowledge of drug diversion from their employer by a fellow employee they have an obligation to report such information to management or by calling 1-888-RITE-CALL. This information, given to management, will be treated as confidential. It should be noted that failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area.

6. Inquiries should be made to local courts and law enforcement agencies for records of pending charges and convictions concerning employees' criminal records.

7. All employees should be made aware of these requirements.

DEA REGULATORY GUIDELINES

XIII. REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES

PURPOSE: To maintain a system capable of correcting errors in inventory and recording and reporting thefts and losses.

PROCEDURE:

1. The General Manager or designee will advise employees of their responsibility to report thefts or significant losses.

2. Every employee must report suspected theft or significant loss of Controlled Substances to the appropriate manager or designee.

3. The DEA Coordinator or designee must immediately notify the General Manager of any theft or significant loss. Significant losses or thefts must be reported to the DEA and your State Board of Pharmacy within 1 business day.

4. After receiving a report of suspected theft or significant loss, or learning of an inventory discrepancy, a thorough investigation will immediately be conducted to determine the cause and amount not accounted for. The DEA Coordinator or designee must discuss with the General Manager the extent of the theft or significant loss.

5. If theft or significant loss at the distribution center is confirmed, the DEA will be contacted with a faxed copy of a suspected loss letter after discussion with and notification of the General Manager and the Government Affairs Department at corporate. Upon notification of the DEA and BOP, complete a DEA "Report of Theft or Loss of Controlled Substances" (DEA Form 106 - **see Attachment A).**

6. Complete the DEA Form 106 and discuss the completed DEA 106 with the General Manager and the Government Affairs Department at corporate prior to forwarding the completed DEA Form 106 to the local DEA office and the appropriate state agency. The DEA form 106 shall be signed by the General Manager. The DEA 106 or an attached memorandum will list those procedures implemented to prevent future thefts or losses.

7. The distribution center will maintain a file folder labeled "DEA 106's" with their Controlled Substance records which contain the following information:

a. The date of each report of suspected theft or loss;

b. A description of the investigation conducted;

c. The results of the investigation;

d. The identity and quantity of drug involved; and

e. A copy of the DEA Form 106.

f. A copy of audit paperwork required for the audit.

8. A copy is forwarded to the Government Affairs Department at RITE AID Corporate Offices.

9. Any losses/discrepancies discovered after accepting an order from a vendor (shipper) that cannot be reconciled must be reported to DEA by the distribution center through a letter of intent. A DEA form 106 will be filed if deemed necessary upon completion of the investigation.

10. In-transit losses discovered upon receipt by the distribution center must be immediately reported to the corporate replenishment department and Government Affairs Department at RITE AID Corporate Offices. Both registrants may be obligated to report the in-transit loss to the DEA.

11. In-transit losses discovered and reported by a pharmacy to the distribution center will be immediately investigated and reported to corporate for an immediate determination on reporting.

DEA REGULATORY GUIDELINE

XIV. MAINTAINING PERPETUAL INVENTORIES

PURPOSE: To account for the receipt, distribution and/or return of Schedule III, IV and V Controlled Substance inventories in order to accurately reflect the exact quantity of each medication on hand at any given time.

PROCEDURE:

1. The employees assigned to the Controlled Substances enclosure will maintain a perpetual inventory on all Controlled Substances located within the approved storage enclosures.

2. On the conclusion of the picking and packing, the employees within the storage enclosure will conduct an inventory of the Controlled Substances on hand and compare this inventory with the perpetual inventory.

3. The employees within the approved storage enclosures will maintain a Schedule III, IV and V Inventory Record. The record will contain the following entries:
   a. employee's name,
   b. date of event which affects inventory,
   c. perpetual inventory.
   d. opening/closing of business.

4. Each time an adjustment is made to the inventory, a designated pharmacy employee enters the required information in the Inventory Record.

5. The designated employees must take inventory of the Controlled Substances on hand, on a daily basis or not less than once a week, to verify that all transactions have been successful and that the Inventory Record is correct.

6. The DEA Coordinator, or other designee of the General Manager, verifies the inventory conducted by the responsible employees, investigates discrepancies, and reconciles them.

7. Discrepancies will be investigated and documented. If the discrepancy cannot be reconciled a determination has to be made if the discrepancy reflects a theft or significant loss.

   NOTE: Any theft or significant loss is reported to the DEA.

8. Maintain the Inventory Record for a minimum of 24 months, or as State law may require.

DEA REGULATORY GUIDELINE

XV. CONDUCTING INVENTORIES

PURPOSE: To conduct and maintain an accurate DEA Biennial Inventory.

PROCEDURE:

DEA INITIAL INVENTORY

1. Upon initial issuance of a DEA registration, the distribution center will conduct a physical inventory of all Controlled Substances on hand. The inventory will be documented to reflect the following information:

   a. Name of each substance;

   b. Each finished form of each substance;

   c. Number of commercial containers;

   d. Volume of or number of units in each container;

   e. Substances damaged, defective, awaiting disposal or return;

   f. The signatures of the employees attesting to the accuracy of the inventory;

2. If no Controlled Substances are in inventory, a "zero" will be indicated.

DEA BIENNIAL INVENTORY

1. Within every two years from May 1, the distribution center will conduct another official DEA biennial inventory recording all Controlled Substances on hand or within its control, including finished, outdated, damaged, defective, awaiting disposal, and those awaiting return to the vendor.

2. It is recommended that another complete inventory be conducted at least every six months (or more frequently at the direction of the General Manager or designee). This may shorten the audit period if a federal or state agency conducts an accountability investigation.

3. The distribution center conducts the inventory every year and records the date on the inventory form. (Example; May 1, 2001; May 1, 2002, etc.)

4. The General Manager or designee is responsible for the

inventory to ensure that the inventory reflects:

a. Name of each substance;

b. NDC (National Drug Code) number

c. Each finished form of each substance;

d. Number of commercial containers;

e. Volume of or number of units in each container;

f. Substances damaged, defective, awaiting disposal or return;

g. The signatures of the employees attesting to the accuracy of the inventory;

h. Date of the biennial inventory;

i. Conducted at the opening or close of business;

j. Names and signatures of the designated individuals taking the inventory.

INVENTORY ADJUSTMENTS

1. Ensure that adjustments to inventories and records are monitored.

a. A system is in place (to meet DEA and PDMA requirements) for correcting all errors in inventory, for reviewing discrepancies and for recording and reporting thefts and losses.

b. The number of employees who have the authority to adjust Controlled Substance on-hand inventories are limited.

c. Records document:
- the investigation conducted, and
- the identity and quantity of drugs lost.

d. A report, documenting the investigation, is completed and approved by the General Manager, prior to the adjustment taking place. Thefts and/or significant losses are reported to the DEA via a DEA 106.

e. Appropriate records (receipt, distribution and inventories) must be issued to reflect any adjustments.

DEA REGULATORY GUIDELINE

XVI. MAINTAINING ACCURATE RECORDS-FILING AND MAINTENANCE

PURPOSE: To meet the requirements for maintaining accurate and up-to-date records for Controlled Substances.

PROCEDURE:

1. All Controlled Substance records, unless approved by DEA for central recordkeeping, must be maintained in a separate location from the other records of the distribution center.

2. DEA has approved a central recordkeeping request for Rite Aid Distribution Centers for the maintenance of Schedule III, IV and V receiving and distribution records to be centrally maintained as outlined in **DRG XVII. Central Records.**

3. The following required inventories/records will be maintained at the distribution center:

   Schedules III, IV and V

   a) The DEA Schedules III, IV and V Initial and Biennial Inventories will be maintained separately from all other records in a file labeled [redacted]

   b) Files relating to Schedules III, IV and V drug destruction (DEA Form 41) and thefts/losses (DEA Form 106) will be maintained in separate files labeled [redacted] respectively.

3. The perpetual inventory records will be maintained separately in an appropriately labeled file for a minimum of two years, or as state law may require.

4. The internal inspection forms will be maintained separately in an appropriately labeled file for a minimum of two years, or as state law may require.

5. The forms documenting employee training of the DRGs will be maintained separately in an appropriately labeled file and in the employee training folder for a minimum of two years, or as state law may require.

6. The forms documenting internal audits will be maintained separately in an appropriately labeled file for a minimum of two years.

7. The memorandums documenting federal and/or state contacts will be maintained separately in an appropriately labeled file.

8. Reports indicating the investigation of suspicious orders will be maintained in an appropriately labeled file.

9. DEA required records will be maintained at the DEA registered distribution center for two years. Some states required records to be retained for up to six years.

   NOTE: Ensure that the retention of your records also meets the state requirements.

Electronic Records

1. For the maintenance of Controlled Substance records the following definition applies:

   a. The term *readily retrievable* means that certain records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner usually identifiable apart from other items appearing on the records.

DEA REGULATORY GUIDELINE

XVII. CENTRAL RECORDS

PURPOSE: To establish a procedure outlining the central recordkeeping requirements as approved by DEA.

PROCEDURES:

1. DEA may permit that financial and shipping records (such as invoices and packing slips) may be kept at a central location, rather than at the registered location, if notified by the registrant of his intention to keep central records.

2. Written notification must be submitted to DEA by registered or certified mail, return receipt requested, in triplicate, to DEA to the Special Agent in Charge in the area in which the registrant is located.

3. DEA has approved central recordkeeping for Rite Aid's distribution centers as per the appropriate notification. This notification shall be kept on file at all distribution centers.

4. The following Schedule III, IV and V records have been approved for central recordkeeping:

   a) Receiving records for Schedule III, IV and V Controlled Substances received at each individual distribution center from the supplier/vendor.

   b) Distribution records for those Schedule III, IV and V Controlled Substances distributed from each individual distribution center to each individual Rite Aid, Thrifty Payless, Harco, Eckerd Corporation and K & B pharmacy.

   c) The distribution records for those Schedule III, IV and V Controlled Substances returned by each individual distribution center to their individual supplier/vendor.

   d) The receiving records for those Schedule III, IV and V Controlled Substances returned by each individual Rite Aid, Thrifty Payless, Harco, Eckerd Corporation and K&B Pharmacy to each individual distribution center.

5. The records, as reference above, will be maintained at Rite

Aid Corporation Corporate Offices.

6. All records approved for central recordkeeping will be maintained in a computer readable form that list the following:

   a) For receiving records, the name, address, and DEA registration number of the supplier, actual date of receipt, drug name, quantity received, strength, dosage form and number of commercial containers,

   b) For distribution records, the name, address, and DEA registration number of the customer, actual shipping date, drug name, quantity shipped, strength, dosage form and number of commercial containers shipped

7. All or part of the computer records will be delivered to the registered location within two business days upon receipt of a written request from the DEA.

8. In lieu of delivering records to the registered location, DEA may inspect the records at the central location upon request.

DEA REGULATORY GUIDELINE

XVIII (A). CONTROLLED SUBSTANCE SECURITY: PHYSICAL SECURITY

PURPOSE: To establish and promulgate minimum requirements for handling and storing Controlled Substances.

PROCEDURES:

1. Controlled Substances shall be stored in a safe, vault, cage or other structure approved by the Drug Enforcement Administration. The type of storage capability will depend upon the schedules of the products.

2. All Controlled Substance storage facilities shall be equipped with either combination, electronic or key lock capability. If key locks are employed there must be a written key control policy in effect. The key control policy must control the assignment of the keys.

3. [redacted]

4. Access to the Controlled Substance storage shall be limited to specifically designated personnel and the names of all such personnel shall be conspicuously posted at the entrance of the storage area.

5. A specific employee(s) shall be designated in writing, by name as an "escort" for the Controlled Substance storage enclosures. The designated employee(s) shall be responsible for ensuring that non-authorized personnel, non-approved employees, visitors requiring access to the Controlled Substance enclosures are escorted at all times.

6. Upon receiving pharmaceutical product a determination will be made as quickly as possible whether there are controlled drugs in the delivery. Once so determined, those products must remain in the custody of authorized and designated employee(s) while processed and removed to the controlled storage area.

7. No Controlled Substance product will be removed from the storage area until it has been properly documented and prepared for delivery. Once ready, a written transfer of custody process shall be employed (not necessary in Woodland and Tuscaloosa for customary shipments via conveyor system).

DEA REGULATORY GUIDELINE

XVIII (B). CONTROLLED SUBSTANCE SECURITY: ELECTRONIC ALARMS

PURPOSE: To establish minimum requirements for electronic protection to prevent unauthorized intrusion to the site and the Controlled Substance storage enclosures.

PROCEDURES:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

DEA REGULATORY GUIDELINE

XVIII(C). CONTROLLED SUBSTANCE SECURITY: ACCESS CONTROL

PURPOSE: To ensure that only authorized employees may access the Pharmacy and Controlled Drug areas.

PROCEDURES:

1. The General Manager or designee shall ensure that every pharmacy department employee, after having completed all hiring requirements, is issued a badge commensurate with the level of access for that employee.

2. An employee shall use his or her proxloc card/digit code and/or key to access any door authorized for that employee. No employee shall enter or exit a designated door on another employees' code.

3. A record of all door openings and closings can be generated by the system. The General Manager or designee shall haphazardly review the record to ensure the records match the authorized access list. If the list does not match than it shall be investigated and resolved.

4. In the event of a known theft or significant loss from inventory, an opening/closing report shall be printed and retained as needed for any investigation process.

5. Any suspected or actual unauthorized disclosure of a personal access code or non-approved transfer of a facility or storage enclosure key must be reported in writing to the General Manager. The report must detail the circumstances of the disclosure or transfer. The General Manager or designee will, upon notification, disable that code or remove the key and issue a new one to the employee. Additional reports of disclosure or unauthorized transfer of a key by the same employee may result in disciplinary action.

6. Visitors will be issued a separate temporary badge as designated by security. Under no circumstances will visitors be given an access code/proxloc card and/or key. **(see DRG XXV. Visitor Controls).**

DEA REGULATORY GUIDELINE

XVIII (D). CONTROLLED SUBSTANCE SECURITY: CCTV & MONITORS

PURPOSE: To establish a policy for the placement and use of CCTVs on the facility and to establish parameters for their use.

PROCEDURES:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

DEA REGULATORY GUIDELINE

XIX. INTERNAL AUDITS FOR SCHEDULE III, IV AND V CONTROLLED SUBSTANCES

PURPOSE: To allow for the accountability and tracking of Controlled Substances.

PROCEDURE:

1. At a minimum on a quarterly basis, Schedule III, IV and V Controlled Substances will be chosen for an accountability.

   - Select an audit period of a minimum of three weeks.
   - It is recommended that three drugs be selected from Schedule III, and two drugs from Schedule IV and one drug from Schedule V.
   - Corporate at times will select the drugs to be audited and will communicate directly with the General Manger or designee.
   - Select different drugs each audit period.

2. On the starting date of an audit, record time of day (opening or closing of business) and the following Controlled Substances are accounted for in actual counts:

   a. Trade

   b. Held for disposal

   c. Outdates, damaged

   d etc.

3. Elements of #2 above are totaled and referred to as beginning inventory.

4. Purchases, returns, (any Controlled Substance which has been received on the premises) are totaled for a given audit period and added to the beginning inventory resulting in a total goods available for distribution for the audit period. "Total Accountable For"

   - Obtain a printout of receipts and compare against the actual receiving records.

5. On the final day of the audit, steps in section two are

repeated and referred to as a closing inventory.

6. Obtain an electronic report and review selected distribution records for the audit period to determine quantity distributed (departed premises).

   - In addition, review DEA 41 or state disposal records and DEA 106 (Theft or Loss Report) to account for Controlled Substances during the audit period.

7. The closing inventory and the quantity distributed (departed premises) are total for the audit period. "Total Can Account For"

8. The Total Accountable For is subtracted from the Total Can Account For.

9. Any difference is reported as + or -.

10. During the audit a review will be conducted of the receiving and distribution records, security and inventories to ensure retrievability and compliance with the regulatory requirements and operating procedures.

11. Findings shall be reported to the General Manager.

DEA REGULATORY GUIDELINE

XX. POLICY REVIEW AND REVISION AND ADMINISTRATIVE ACTIONS

PURPOSE: To allow for suggested changes, revisions, updates or to identify areas/operations for new procedures.

PROCEDURE:

1. DEA Coordinators or designee(s) are required to read the DEA REGULATORY GUIDELINES (DRGS) at least once a year and receive the proper training in the requirements of the DEA REGULATORY GUIDELINES.

2. This review will be utilized to institute any required revisions, updates, changes or preparation of future procedures.

3. The staff is encouraged to suggest changes, revisions, updates or identify the area for new procedures at any time and forward the comments to the General Manager.

4. No changes or re-writes to "DEA REGULATORY GUIDELINES" will be tolerated unless approved by Corporate. Failure of any staff member to implement and follow the "DEA REGULATORY GUIDELINES" could lead to progressive disciplinary action.

DEA REGULATORY GUIDELINE

XXI. HOW TO HANDLE A DEA INSPECTION

PURPOSE: To insure that the distribution center handles a DEA inspection in compliance with the regulatory and standard operating requirements.

BACKGROUND:

RITE AID's intention is to make CSA compliance as easy and efficient as possible, which in turn will make the task of the DEA easier. Despite an inclination by other registrants to consider a regulation as burdensome, the legislative and social intent of regulating Controlled Substances is consistent with our mission in serving the public good. To achieve these important goals, we and the DEA have to continue to build an effective professional regulatory partnership that supports the proper and appropriate use of Controlled Substances for legitimate medical use and seeks to eliminate any and all diversion of Controlled Substances for inappropriate and illicit use.

The Comprehensive Drug Abuse Prevention Act (Public Law 91 5132, the "Controlled Substances Act of 1970," or the CSA) authorized the Drug Enforcement Administration (DEA) to enforce provisions of this Act as they apply to registered handlers of Controlled Substances.

The Diversion Control Program of the DEA (and its predecessor agencies) was established to enforce the provisions of the CSA and the implementing regulations as they apply to registered handlers of Controlled Substances (manufacturers, distributors, pharmacies, practitioners, importers, exporters, hospitals, analytical laboratories, and researchers).

DEA registered distributors must ensure that they are in full compliance with DEA requirements and/or take immediate corrective action before the DEA investigates our distribution center. Therefore we must and will review and confirm adherence to DEA requirements and undertake selected checks of Controlled Substances compliance at a minimum of once a year to uncover and correct violations of the CSA and its implementing regulations. **(Compliance with DEA requirements is an on-going process that deserves and requires continued attention. The more frequently all aspects of DEA compliance are reviewed, the better the chances that we will be in compliance and not experience problems when DEA or others review our operation.)**

PROCEDURES:

Like any regulatory agency, the DEA conducts its activities to ensure that the law and its underlying public policy goals are being met. **A regulatory investigation by the DEA must be taken**

seriously, because it is serious and because the actions the DEA has at its disposal if we are found in violation of DEA requirements can be very costly, in many ways.

1. The General Manager, accompanied by a manager knowledgeable in CSA requirements, and the DEA Coordinator, must always accompany and work closely with the DEA investigators.

2. Quick Review

   a. The basis for DEA authority derives from the Comprehensive Drug Abuse Prevention Act.

   b. DEA enforcement activities encompass all registered handlers of Controlled Substances.

   c. The DEA's goals are to prevent mis-diversion of Controlled Substances and to ensure adequate supplies for legitimate medical use.

   The DEA conducts periodic investigations of CSA registrants. **IF THE DEA ARRIVES TO CONDUCT A REVIEW, IMMEDIATELY CONTACT THE GENERAL MANAGER.**

   e. Violations can result in direct actions against DEA registrants.

   f. The DEA has a number of actions at its disposal to counter registrant violations, including administrative, licensing, civil, and criminal actions.

   g. Individual DEA registrants are responsible for ensuring their compliance with DEA requirements.

   h. DEA registrants must review their procedures and records to detect and correct any shortcomings; frequent reviews are prudent.

   i. DEA investigations demand close attention by knowledgeable staff, who will accompany and work closely with DEA investigators at all times.

   j. DEA investigators usually utilize a Notice of Inspection to enter a registered location. If they anticipate a problem or violations they will usually obtain an Administrative Inspection Warrant or a Search Warrant.

3. While comprehensive, DEA requirements are not difficult to meet if they are viewed as a continuous process. The

following steps will help:

a. Get to know and keep up with the Controlled Substances Act and DEA requirements.

b. Continually stress and demonstrate proper DEA compliance to our staff as a means of setting high standards.

c. Use the DEA REGULATORY GUIDELINES (DRGs) for all DEA requirements in our facility to ensure continuous and complete adherence to all requirements.

d. Evaluate our staff on the basis of error-free compliance.

e. Make absolutely sure that our DEA-required records are current, complete, and correct and that those employees who will coordinate a DEA inspection are aware of their location.

f. Train all new staff - (even if they are experienced) - on our DEA DRGs and our expectations for full compliance. **(Do not assume that just because someone has experience that they know and are used to complying with DEA requirements. You cannot afford to ignore this area simply because you are uncomfortable introducing the subject with colleagues.**

g. Do not overlook temporary or "relief" staff who work in our operation; they can make errors too, and their errors are still our responsibility as the registrant.

h. Re-train, re-emphasize, re-state your expectations periodically. Time has a way of producing unintended and often undetected "slippage" that can be very costly when it comes to DEA violations.

i. Conduct periodic pre-inspection audits so that we may correct any shortcomings in procedures, recordkeeping, and reporting requirements before the DEA inspection.

THE DEA INVESTIGATION

1. Cooperate with DEA investigators; respond to their questions.

2. If a DEA investigator requests a record, retain a copy

for our files.

3. If the DEA conducts an inventory of selected Controlled Substances to conduct an accountability, agree to the count.

4. As DEA conducts their accountability complete our own accountability - **THERE SHOULD BE NO SURPRISES.**

5. At the end of each day prepare a report of that day's activity and forward a copy to the Government Affairs and Regulatory Compliance Department.

6. If any violations are discovered by DEA during the review notify the General Manager, Government Affairs, and Regulatory Compliance Departments and immediately correct and advise the investigators and document.

7. Know what records, issues and areas that DEA is reviewing.

8. Try to discuss and correct any violations identified by the DEA.

9. Request a discussion at the completion of the review to discuss DEA's findings and, if possible, our corrections.

10. Prepare a report at the end of the review, to include findings, drugs audited, records, reports, discussions, DEA comments and recommendations, etc. and forward a copy to the Government Affairs and Regulatory Compliance Departments.

Because the DEA may review a registrant at any time, our chances of being visited increases the longer we go without a visit from the DEA. Rest assured that the DEA investigator will be prepared when he or she arrives; can we confidently say that we are ready too? All deficiencies and errors that we correct today mean a trouble-free inspection tomorrow.

Any DEA investigation must be considered serious, so we will assign an appropriate and knowledgeable employee to work closely with DEA investigators.

Upon arrival of the investigators at the registered locations, the General Manager or their designee and the DEA Coordinator should meet with the investigators as soon as possible, review their credentials and accept the DEA Notice of Inspection. A discussion should then be held regarding the purpose and extent of the investigation and the desire of management for a close-out discussion at the completion of the investigation.

Authority of the DEA Investigator

21 USC 880 and Section 1316.03 allow DEA investigators to enter a registered location (controlled premises) upon stating their purpose and presenting credentials and a written notice of inspection or, if warranted, an administrative inspection warrant for the purpose of:

- Inspecting and copying records, reports and other documents required to be kept or made;
- Inspecting, within reasonable limits and in a reasonable manner, all pertinent equipment, Controlled Substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Controlled Substances Act;
- Conducting a physical inventory of all Controlled Substances on the premises;
- Checking records and information regarding receipt, distribution and dispensing of Controlled Substances by the registrant.

An administrative inspection warrant is not required if informed consent is obtained from the registrant. It is our policy to accept the Notice of Inspection.

The General Manager, DEA Coordinator and a manager who is familiar with the DEA recordkeeping and reporting requirements and security in place must always accompany the investigators.

The person that accompanies the DEA investigators will be prepared to:

- Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting these areas;
- Explain the operation/type of security, recordkeeping and reporting systems/procedures maintained;
- Assist the investigators;
- Verify the accuracy of the information the investigators obtain from inventories, sales and purchase documents and make a list of the records reviewed;
- Obtain copies for and retain copies of any

documents the investigators request;

- Assure that information volunteered is clearly beneficial to the registrant;
- Assure that no misrepresentations are given to the investigators;
- Note any suggestions or criticisms expressed by the investigators. Any violations discovered in this manner should be corrected immediately and documented;
- Prepare a report on the investigation with findings. The registrant using this report and statements made by the investigator should reconstruct the investigation to verify any violations or, as is possible, reveal no violations. A copy of this report will be forwarded to the Government Affairs and Regulatory Compliance Departments

Discussions with management will usually be used by DEA to reinforce the findings by acquiring the registrant's acceptance of the cited violations and willingness to correct them or the registrant's challenge of the findings by non-acceptance of the violations.

If the DEA intends to take further action, the registrant may or may not be informed of what courses of action are possible.

It should be noted that DEA is not required to conduct a closing discussion at the completion of the investigation. If not initiated by the investigator, the registrant should request a closing discussion at the convenience of the investigator. If this fails, it is suggested that a request be made to the investigator's supervisor; expressing the desire to meet and discuss the findings and any corrective action that may be required.

If the registrant cannot obtain a closing discussion, the report prepared by the employees assigned to accompany the investigator during the investigation should be utilized to reconstruct the investigation and findings.

Once aware of any violations, the registrant should take the following initiatives in seeking and implementing corrective actions:

- Reconstruct the investigation and findings, using the same documents, facility review utilized by the investigators and the

registrant's internal report;

- Take appropriate action to correct any violations or problems uncovered during the DEA investigation;

- Convey to DEA the corrective action taken, what steps the registrant has taken to prevent future problems and inquire what further action the registrant should take.

It is suggested that if a registrant investigation disagrees with the DEA investigation, they should contact DEA immediately and request a meeting to discuss the findings.

If violations are found, it may be possible to negotiate with the DEA or the Assistant U.S. Attorney. If there is a problem, consult with the Government Affairs and Regulatory Compliance Departments.

DEA REGULATORY GUIDELINE

XXII. COORDINATION WITH REGULATORY AND ENFORCEMENT AGENCIES

PURPOSE: To insure that we coordinate with the Government Affairs and Regulatory Compliance Departments prior to or upon contact with a regulatory or enforcement agency.

BACKGROUND:

This procedure is written in response to a need for a single source of current information for our operation regarding contact with state or federal regulatory or enforcement agencies.

With our substantial growth, it is vital that consistency in operational procedures be maintained to the best of our ability.

By fully implementing and adhering to the DEA REGULATORY GUIDELINES, as well as state and federal requirements, that consistency can be maintained.

PROCEDURES:

To ensure consistent implementation of the state and federal requirements we will adhere to the following procedures:

1. Assure that all operating procedures are fully implemented.

2. A logbook will be maintained to document any and all contact with any government agency (BOP, FDA, DEA, etc). This will ensure compliance on a uniform basis and prevent inconsistent implementation of our operating procedures as well as state and federal requirements.

3. In an emergency, the General Manager or designee is authorized to immediately contact the local law enforcement agencies. This is to be followed with a verbal and then a written report to the Government Affairs and Regulatory Compliance departments.

DEA REGULATORY GUIDELINE

XXIII. STAFF TRAINING

PURPOSE: To require training for staff in the requirements of the DEA REGULATORY GUIDELINES (DRGs).

PROCEDURE:

1. The General Manager is responsible for assuring that the DRGs are implemented.

2. The General Manager or designee is responsible for immediately establishing a training program and schedule for assuring that employees involved in the receiving, storage, and delivery of Controlled Substances are familiar with and understand the requirements for their operation.

   a. Upon development of your training program and training schedule, forward a copy to the Distribution Center General Manager for approval.

   b. It is our intention that the training will be ongoing and continual. There will be no exceptions to the training requirement.

3. A training form that contains the following information will be utilized:

   a. Employee name

   b. Date of training

   c. Topics for which the training was conducted

   d. Signature of employee confirming the training and acknowledging that they understand the requirements.

4. All employees new to either the general pharmacy department or to the Controlled Drug area will be trained within their first week of transfer.

DEA REGULATORY GUIDELINE

XXIV. LIST I CHEMICALS

PURPOSE: To ensure that the regulatory requirements for handling products that contain List I chemicals are implemented.

PROCEDURE:

1. We are required to maintain records for the distribution of those drugs that contain List I chemicals and submit reports as required.

2. The records must be maintained for two years, or as state law requires, after the date of the transaction and must be maintained at the distribution center where the transaction occurred unless a central records keeping agreement exists.

3. The records required to be kept pursuant to the regulatory requirements must be readily retrievable and available for inspection and copying by authorized employees of the DEA.

4. The following are the List I chemicals:

   a. Anthranilic acid and its salts

   b. Benzyl cyanide

   c. Ergonovine and its salts

   d. Ergotamine and its salts

   e. N-Acetylanthranilic acid and its salts

   f. Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers

   g. Phenylacetic acid and its salts

   h. Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers

   i. Piperidine and its salts

   j. Pseudoephedrine, its salts, optical isomers, and salts of optical isomers

   k. 3, 4-Methylenedioxyphenyl-2-propanone

   l. Methylamine and its salts

m. Ethylamine and its salts

n. Propionic anhydride

o. Isosafrole

p. Safrole

q. Piperonal

r. N-Methylephedrine, its salts, optical isomers, and salts of optical isomers

s. N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers

t. Hydriotic acid (57%)

u. Benzaldehyde

v. Nitroethane

5. The records and reports required by the regulations must contain the following information:

a. The name and address of each party to the regulated transaction.

b. The date of the regulated transaction.

c. The name, quantity and form of packaging of the listed chemical.

d. The method of transfer (company truck, picked up by customer, etc.).

e. The type of identification used by the purchaser and any unique number on that identification.

6. Normal business records will be considered adequate by the DEA if they contain the information listed above and are readily retrievable from other business records of the regulated person.

7. For prescription drug products, records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205 of the Code of Federal Regulations Parts 200 To 299, Revised as of April 1998, will be considered adequate for satisfying the requirements with respect to wholesale distributions.

8. We are required to report to the Special Agent in Charge of the DEA Divisional Office for the area in which we are located, as follows:

a. Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the regulatory requirements.

- It is extremely important that we monitor our distributions to pharmacy locations to ensure that excessive quantities are not distributed.
- Corporate legal will develop a distribution threshold. The threshold will be utilized to determine suspicious orders.
- Bring possible excessive quantity orders or questionable requests immediately to your management prior to picking the order.
- Management will contact the customer to discuss the order and the need for the ordered quantity.
- The discussions will be documented and brought to the General Managers attention for a resolution and/or report to the Government Affairs and Regulatory Compliance Departments if suspicious.

b. Any proposed regulated transaction with a person whose description or other identifying characteristic the DEA has previously furnished to the regulated person.

c. Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person is responsible for reporting a loss in-transit is the supplier.

9. Each report submitted pursuant to the regulatory requirements must, whenever possible, be made orally to

the DEA Divisional Office for the area in which we are located at the earliest practicable opportunity after we become aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible.

a. Written reports of transactions will subsequently be filed within 15 days after we become aware of the circumstances of the event.

b. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to us by the DEA unless the transaction is approved by the DEA.

10. Our reports must include the information as specified above and, where obtainable, the registration number of the other party, if the party is registered. The report submitted must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance, the circumstances of the loss must also be provided (in-transit, theft from premises, etc.).

11. The following is a suggested format for the reports:

Supplier:

Name _____

Business Address _____

City _____

State _____

Zip _____

Business Phone _____

Purchaser:

Name _____

Business Address _____

City _____

State _____

Zip _____

Business Phone _____

Identification _____

Shipping Address (if different than purchaser address):

Street _____

City _____

State _____

Zip _____

Date of Shipment _____

Name of Listed Chemical(s) _____

Quantity and Form of Packaging _____

Description of Machine:

Make: _____

Model: _____

Serial # _____

Method of Transfer _____

If Loss or Disappearance:

Date of Loss _____

Type of Loss _____

Description of Circumstances _____

12. Every person who distributes, imports or exports a List I chemical or a product that contains a List I chemical must obtain annually a registration specific to the List I chemicals to be handled.

- Since our Pharmacy Centers possess a DEA registration as a distributor of Controlled Substances we are not required to obtain an additional registration for the purpose of distributing products that contain List I chemicals.

DEA REGULATORY GUIDELINE

XXV. VISITOR CONTROLS

PURPOSE: To ensure that non-employee accessibility to the facility is limited and strictly enforced for reasons of security and safety.

PROCEDURES:

1. All visitors must be admitted into the building by the security or other designated employee.

2. Every visitor must sign the Visitor Log. It should include the following headings: date, name, representing, contact, time in, time out, badge number and signature.

3. The contact person is advised that a visitor is on site. It shall be the responsibility of the contact person to then personally escort or provide an escort for the visitor at all times.

4. If the visitor is to be admitted to any Controlled Substance storage area, the person designated as the "authorized escort" for that area shall escort the visitor at all times in that area.

5. At the conclusion of the visitor's business on-site he/she shall sign out of the Visitor's Log.

6. All employees shall be advised and periodically reminded to challenge all unescorted non-employees. If such a person is observed he/she will accompany the visitor to his/her supervisor. If the employee cannot leave his/her position the visitor will remain in place while the supervisor is called. In either case the supervisor will escort the visitor to the appropriate Manager for resolution of the incident.

   Consideration will be given to preventing this unescorted person from having future access to the facility.

DEA REGULATORY GUIDELINE

XXVI. ARCOS

PURPOSE: To establish a procedure to ensure the activities involving Schedule II, III, and IV narcotic Controlled Substances are reported in the appropriate manner to meet the regulatory requirements.

PROCEDURE:

1. ARCOS provides for the audit of drug inventory acquisition/distribution transactions that are originated by manufacturers and distributors of Controlled Substances.

2. All transactions to and from another DEA registrant that involve sale, purchase, destruction, loss/theft for any ARCOS-reportable substance are to be reported.

3. ARCOS will be reported by RITE AID on a monthly basis. Reports will be filed every month not later than the 15th day of the month succeeding the previous month for which it is submitted.

4. Information will be submitted to DEA by a method of electronic file transfer.

5. Inventories shall provide data on the stocks of each reported Controlled Substance on hand as of the close of business on December 31 of each year. This report shall be filed not later than January 15 of the following year and be included in the December report for monthly reporters.

6. Each calendar year, monthly reporters shall submit no more than 12 reports to ARCOS.

7. If no ARCOS reportable inventory is on hand on December 31, a report shall be submitted with transaction code '8'-No Year End Inventory in the December report.

8. Four major categories of transaction codes are used in reporting. They are as follows:

   Inventory

   Code 1 = Schedule Change Inventory
   Code 3 = Year-end Inventory
   Code 5 = Special Inventory
   Code 8 = No Year-end Inventory

Acquisition

Code P = Purchase or Receipt
Code R = Return
Code V = Unsolicited Return
Code G = Government Supplied

Disposition

Code S = Sale, Disposition, or Transfer
Code Y = Destroyed
Code T = Theft
Code Z = Receipt by Government (seizures, samples, etc.)

Miscellaneous

Code 7 = No ARCOS Activity for Current Reporting Period
Code F = Reorder DEA Form 333
Code X = Lost in Transit

9. Details on the procedures for each transaction will be followed as described in the ARCOS Registrant Hand Book.

10. Errors as detailed in the Edit Error Report should be corrected and submitted with the next regular ARCOS report.

11. The appropriate DC can request from the Corporate Office verification of Receipt of ARCOS reports.

12. Compare the primary receiving and distribution records with the ARCOS reports to ensure that the dates of activity are the same.

- The receiving and distribution records and ARCOS reports must list the actual date the Controlled Substances are received and distributed from the DEA registered facility.

DEA REGULATORY GUIDELINE

XXVII. FREIGHT FORWARDING

PURPOSE: To establish a procedure to ensure the activities involving freight forwarding are conducted in the appropriate manner to meet the regulatory requirements.

PROCEDURE:

1. Freight forwarding (as used in DEA's regulatory meaning does not have the same meaning that it carries in the transportation/distribution industry) means a separate facility operated by a distributing registrant through which sealed, packaged Controlled Substances in unmarked shipping containers (i.e., the containers do not indicate that the contents include Controlled Substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours.

2. A distributing registrant may operate a freight forwarding facility to transfer Controlled Substances from any location the distributing registrant operates that is registered with the DEA to distribute Controlled Substances, or, with respect to returns, registered to dispense Controlled Substances, provided that the required notice has been submitted and approved.

3. The registration requirement for a freight forwarding facility is waived provided that the distributing registrant submits proper notice to DEA of the intent to operate the facility.

4. The distributing registrant shall submit a written notice of intent to operate the facility by registered mail, return receipt requested, to the Special Agent in Charge of the Administration's office in both the area in which the facility is located and each area in which the distributing registrant maintains a registered location that will transfer Controlled Substances through the facility. The notice shall detail the following:

   a. the registered locations that will utilize the facility;
   b. the location of the facility;
   c. the hours of operation;
   d. the individual(s) responsible for the Controlled Substances;
   e. the security and recordkeeping procedures that will be employed; and
   f. whether Controlled Substances returns will be processed through the facility.

5. In addition, the notice must also detail what state licensing requirements apply to the facility and the registrant's actions to comply with such requirements.

6. Notice of approval or disapproval will be provided by DEA within 30 days after confirmed receipt of the notice.

7. Controlled Substances that are being transferred through a freight forwarding facility may be stored in the facility for less than 24 hours.

8. Storage of Controlled Substances for 24 hours or more does not meet the definition of a freight forwarding facility and does not qualify for waiver of the registration requirement.

9. Containers with Controlled Substances must be kept under continuous observation during storage by designated individuals or maintained in a secured area that was approved by the DEA in the Memo of Understanding agreement between Rite-Aid Corporation and the DEA.

10. Access to Controlled Substances must be kept to an absolute minimum number of specially authorized individuals. Non-authorized individuals may not be present in or pass through Controlled Substances storage areas without adequate observation provided by an individual authorized in writing by the registrant.

11. Records are required to be maintained by the distributing registrant utilizing the freight forwarding facility regarding the transfer of Controlled Substances through the facility. The records must reflect the following:

    a. Date;
    b. Time of transfer;
    c. Number of cartons, crates, drums, or other packages in which Controlled Substances are shipped; and
    d. Authorized signatures of each transfer.

12. Each shipment shall contain the usual documentation of Controlled Substances in the shipment i.e., invoices, packing slip, etc.